The following corrections or additions to the January 2004 list were published in the Federal Register in October 2004.

New Approvals

ANADA Number: 200-272

Pioneer Product:	140-841
Trade Name:	Noromectin® Pour-On for Cattle
Ingredients:	Ivermectin
Sponsor:	Norbrook Laboratories, Ltd.
Approval Date:	September 13, 2004
Status:	Over-the-counter
Route:	Topical
Species:	Cattle
Drug Form:	Liquid (solution)
Concentration:	5 milligrams per milliliter
Indications:	For the control of: **Gastrointestinal Roundworms:** *Ostertagia ostertagi* (adults and L4) (including inhibited stage), *Haemonchus placei* (adults and L4); *Trichostrongylus axei* (adults and L4); *T. colubriformis* (adults and L4); *Cooperia spp*. (adults and L4); *Strongyloides papillosus* (adults); *Oesophagostomum radiatum* (adults and L4); *O. venulosum* (adults only); *Trichuris spp*. (adults). To control infections for 14 days after treatment for *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora.* **Lungworms:** *Dictyocaulus viviparus* (adults and L4) **Cattle Grubs (parasitic stages):** *Hypoderma bovis; H. lineatum* **Mites:** *Sarcoptes scabiei var. bovis* **Lice:** *Linognathus vituli*; *Haematopinus eurysternus; Damalinia bovis; Solenopotes capillatus* **Horn Flies:** *Haematobia irritans*
Tolerance:	*21CFR 556.344* Ivermectin: A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) as 100 parts per billion in liver and 10 parts per billion in muscle.
Withdrawal:	48 days. A withdrawal time for milk and pre-ruminating calves has not been established.

21CFR 524.1193

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 101-479

This supplemental application provides for use of flunixin in lactating dairy cattle for control of pyrexia associated with respiratory disease and endotoxemia, and for control of inflammation from endotoxemia. This supplement also provides for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk.

Trade Name:	Banamine® Injectable Solution
Ingredients:	Flunixin meglumine
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	August 19, 2004
Status:	Prescription only
Route:	Intravenous
Tolerance:	*21CFR 556.286*: Flunixin meglumine: A tolerance is established for parent flunixin free acid of 0.125 part per million in cattle liver (target tissue), 0.025 part per million in cattle muscle, and 2 parts per billion in milk.
Exclusivity:	3 years
Withdrawal:	Meat - 4 days; milk - 36 hours

21CFR 522.970 & 556.286

NADA Number: 134-314

This supplemental application provides for revised labeling. The sub-heading Small Strongyles, has been revised to separate the listing of adult species from the fourth-stage larvae.

Trade Name:	Eqvalan® Paste 1.87%
Ingredients:	Ivermectin
Sponsor:	Merial Ltd.
Approval Date:	August 9, 2004
Status:	Over-the counter
Route:	Oral
Species:	Horses, not for food

21CFR 520.1192

ANADA Number: 200-247

This supplemental application provides for the additional use in a new species, finfish fry and fingerlings, for skeletal marking by immersion as an aid in identification.

Trade Name:	Oxytetracycline HCl Soluble Powder - 343
Ingredients:	Oxytetracycline hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	September 15, 2004
Status:	Over-the-counter
Route:	Immersion
Species:	Finfish (fry and fingerlings)
Drug Form:	Powder
Indications:	For the marking of skeletal tissues in finfish fry and fingerlings as an aid in identification.
Tolerance:	*21CFR 556.500:* Oxytetracycline: Tolerances are established for the sum of residues in tissues and milk for beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, finfish, and lobsters as follows: 6 parts per million in liver, 12 parts per million in fat and kidney, 0.3 part per million in milk, and 2 parts per million in muscle.
Withdrawal:	A withdrawal time beyond the grow-out period is not needed.

21CFR 529.1660

ANADA Number: 200-265

This supplemental application provides for the over-the-counter marketing of praziquantel tablets in 5, 10, and 50 tablet container sizes.

Trade Name:	Prazi-C Tablets
Ingredients:	Praziquantel
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	September 15, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Dogs
Drug Form:	Tablets
Concentration:	34 milligrams per tablet
Indications:	For the removal of tapeworms; *Dipylidium caninum* and *Taenia pisiformis.*

21CFR 520.1870

Change of Sponsor

NADA Number: 006-391, 006-677, 007-087

From: Hess & Clark, Inc.

To: Phoenix Scientific, Inc.
Drug labeler code: 059130

NADA Number: 033-773, 109-471, 136-214

From: Sweetlix LLC

To: Ridley U.S. Holdings, Inc.
424 North Riverfront Dr.
P.O. Box 8500
Mankato, MN 56002-8500
Drug labeler code: 067949

Change of Sponsor's Address

Alpharma Inc.
One Executive Dr.
Fort Lee, NJ 07024
Drug Labeler Code: 046573

Intervet Inc.
29160 Intervet Lane
P.O. Box 318
Millsboro, DE 19966
Drug Labeler Code: 057926

Vétoquinol N.-A., Inc.
2000 chemin Georges
Lavaltrie (PQ)
Canada J5T 3S5
Drug Labeler Code: 059320

Suitability Petition Action

Number:	04P-0372/CP1
Sponsor:	Intervet Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristic(s): The generic product will have a different dosage form (chewable tablet) from the pioneer.
Action:	Approved on October 8, 2004.

Number:	04P-0127/PRC1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission for reconsideration to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristic(s): The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.
Action:	Denied on October 27, 2004.

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a correction of sponsor's drug labeler code for Pennfield Oil Co. from 053389 to 048164. This rule is effective October 26, 2004. FDA has found that the animal drug regulations do not reflect the correct sponsor's drug labeler code for Pennfield Oil Co. Accordingly, the agency is amending the regulations in 21 CFR 510.600, 520.445b, 520.1660d, 522.1660a, 558.76, 558.78, 558.128, 558.140, 558.145, 558.195, 558.355, 558.450, 558.550, 558.600, 558.625, and 558.630 to correct this error.
Pennfield Oil Co.
14040 Industrial Rd.
Omaha, NE 68144
Drug Labeler Code: 048164

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 500 to 599, revised as of April 1, 2004, on page 331, in Sec. 529.1940, paragraph (e)(2)(ii) is corrected beginning in the fourth line, by removing sections (1) and (2).